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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,872	10/12/2001	Anthony Toranto	ANGL-06602	2860

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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER
DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
1641	9

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,872	TORANTO ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-27 in Paper No. 8 is acknowledged.

Claim Objections

2. Claim 19 is objected to because of the following informalities: The word "know" should be "known". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is vague and indefinite because it is not clear as to how the detectable signal is being detected at the reaction site. Is the reaction site reacted with any other

reagents to make detection signal visible. In other words, what will bind the saliva to allow a detectable signal?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 6, 11 rejected under 35 U.S.C. 102(b) as anticipated by Vodian et al (USP#4,853,325).

Vodian et al teaches a saliva test for feline leukemia virus (FeLV) that employs an immunochemically sensitive probe that is inserted in the oral cavity of a cat. ELISA reagents are employed for incubation of probe and development of color reactions to indicate the presence or absence of FeLV with the saliva sample (col. 2, lines 62-68). The immunological probe is coated with an anti-FeLV antibody as recited in claim 6 (col. 5, lines 20-28). The color change is visible as a positive color development on the test submember indicates the presence of FeLV and/or FeLV antigens in the saliva sample as recited in claim 11(col. 5, lines 4-8).

8. Claims 1-6 and 11, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Manautou et al (USP#3,875,013).

Manautou et al teaches a test that provides for detecting the fertile period or the presence of pregnancy in a female. In one embodiment, the saliva of a female is tested orally, in which her tongue wets the test paper and waits about 20 minutes forming a color. The test strips are impregnated with reagents for the practice of the invention as recited in claims 1-6 (col. 3, lines 20-25). The test strips is then compared to a standard color card that has a series of color spots similarly developed from known concentrations of the color compound p-nitrophenol (chromogen) as recited in claims 2, 11 and 16 (col. 3, lines 39-58).

9. Claims 1-5, 8-12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jangbir S. Sangha (USP#5,334,502).

Jangbir S. Sangha teaches a method for rapidly determining saliva that can be analyzed for an analyte. A sample probe (strip) comprising a support stick is inserted into the mouth of a subject and saliva put onto an absorbent and upon saturation will approach an indicator and undergo a color change as recited in claims 1-4 (col. 8, line 37, to col. 9, line 5). Upon the appropriate amount of saliva saturated on the sample portion of the absorbent, detection of an analyte such as HIV and other analytes of interest are determined as recited in claim 1 (col. 9, lines 1-5). A color change will occur upon contact with components (analytes) in saliva in the sample portion of the absorbent as recited in claim 5 (col. 8, lines 46-49). The present method takes advantage of the ability of the peroxidase enzyme in saliva in the presence of peroxide to oxidize the leuco or colorless form of a dye or other forms that produce color as

recited in claims 8 and 10 (col. 4, lines 14-20). A chromogen may be one of several compounds that produce a color at the reaction site as recited in claims 9 and 16 (col. 6, lines 12-15). The on-site examiner can observe a color change upon contact with saliva or components of saliva as recited in claims 11 and 12 by wicking the absorbent upward in the mouth of the subject and viewing a change in the indicator (col. 8, lines 37-52).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 6, 13-15 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jangbir S. Sangha (USP#5,334,502) in view of Stuart C. Bogema (USP#6,248,598).

The teachings of Jangbir S. Sangha are set forth above and differ from the instant invention by not specifically pointing out that the reaction site comprise of an antibody or the length of time reaction site is held in the mouth of the subject.

However, Stuart C. Bogema teaches a device that provides a rapid analysis of saliva samples while also providing a convenient assay method that can be used by non-laboratory personnel without risk of user errors (see abstract). A solid support (strip) made of a suitable absorbent material is inserted into the patient's mouth that

provides for sufficient absorption of saliva for about 10-120 seconds (col. 7, lines 15-65). A portion of the solid support (strip) includes a visual reading area on which is directly bound a binding partner, a protein such as an antibody that specifically binds an analyte that comprise of a colored label (col. 8, lines 12-23). The results can be seen with the naked eye (col. 8, lines 52-54).

It would have been obvious to one of ordinary skill in the art to incorporate an antibody as taught by Stuart C. Bogema and utilize it in the reaction site of the test strip as taught by Jangbir S. Sangha to specifically bind the analyte being detected in the saliva. It would have also been obvious to one of ordinary skill in the art to modify the test strip of Jangbir S. Sangha to perform an assay test quickly and simply thereby eliminating the need for a technician or a laboratory setting that should afford benefits both in terms of convenience and reduced costs. With respect to claims 20-27, which are features of remaining dependent claims that are either specifically described by the references (e.g., ethanol, methanol detection col. 11, line 11) or constitute obvious variations which are routinely modified in the art and which have not been described as critical to the practice of the invention, it would have been further obvious to one having ordinary skill the art at the time the invention was made to modify the method of Jangbir S. Sangha to detect any known analyte of interest, especially since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. In re Stevens, 101 USPQ 284 (CCPA 1954). Absent evidence to the contrary, the detection of known analytes in the instant invention is viewed as routine optimization of the prior

art method as described in Jangbir S. Sangha in view of Stuart C. Bogema to detect a particular analyte of interest.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jangbir S. Sangha in view Andrew Kindler (USP#5,494,831).

The teachings of Jangbir S. Sangha are set forth above and differ from the instant claim in not teaching the use of a biosensor.

However, Andrew Kindler teaches an electrochemical immunosensor (biosensor) which uses electrical signals to measure binding events. Signal generating means develop an electrical signal at the sensing electrode such that a response current is produced through the sensing electrode. The response current has measurable signal that are dependent upon the number of complexes formed within the sample concentration (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Jangbir S. Sangha to include the use of a biosensor as taught by Andrew Kindler to not only detect the analyte in a sample, but to also measure quantities of the binding events (col. 3, lines 30-40).

13. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jangbir S. Sangha (USP#5,334,502) in view of Mennen et al (USP#4,562,043).

The teachings of Jangbir S. Sangha are set forth above and differ from the instant claims in not pointing out that the chromogen used in the assay is non-toxic.

However, Mennen et al teaches a self-contained swab cartridge apparatus for detecting occult blood (see abstract). The object of this invention is to provide a practical device to improve testing by the ability to use a non-toxic chromogen rather than a toxic chromogen in an apparatus which makes the handling of the non-toxic chromogen much safer than in the normal testing methods using a paper strip or in the testing on a microscope slide with an time limitation on color development protocol.

It would have been obvious to one of ordinary skill in the art to use the non-toxic chromogen as taught by Mennen et al with the method of Jangbir S. Sangha for safe handling of sample testing in hospitals, clinics and laboratory settings (col. 3, lines 6-11). Although the reference of Mennen et al does not explicitly teach that said chromogen is non-toxic and not a known carcinogen, with respect to claims 18 and 19, it would have been further obvious that the teachings of the instant reference would encompass these known safety features, especially when patient is undergoing oral testing for detection of an analyte wherein said test utilizes a chromogen, as taught by Jangbir S. Sangha, one skilled in the art would assume that a chromogen that is non-irritating and one that is not a known carcinogen will be utilized.

Conclusion

14. For reasons aforementioned, no claims are allowed.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Henry Tom (USP#4,444,880) teaches a solid support dipstick immunoassay having a peroxidase signal producing system.

B. Robert M. Friedenberg (USP#4,915,639) teaches a drug abuse dipstick comprising a stain-producing reagent, which will react with the various drug abuse compounds to form colored products.

C. Mervin J. Moldowan (USP#4,962,025) teaches a reagent alcohol test strip device having a reaction site, a sample collector or metering site and color blocks to indicate the presence or amount of a substance in a sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
December 2, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/02/02